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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/587,428

04/18/2007

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EXAMINER

SEIFU, LESSANEWORK T

ART UNIT

PAPER NUMBER

1797

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/587,428	<b>Applicant(s)</b> ENGSTROM ET AL.	
	<b>Examiner</b> Lessanework Seifu	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 July 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/07/06</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 5-9, and 11-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Thomas et al. (WO 99/55827).

Note: The reference made below to Thomas et al. is to U.S. Patent No. 6,632,656 which is an equivalent of the reference WO 99/55827 above.

Regarding claims 1, 2 and 5-9, Thomas et al. disclose a microfluidic device comprising a microchannel structure having a plurality of flow paths (see Figs. 1b, 2, and 3). Thomas et al. disclose that each of the flow paths can comprise a section (chamber 3, 11) comprising a first porous bed (see col. 8, lines 52-60). Thomas et al. disclose that the first porous bed exposes an immobilized reactant that is capable of interacting with a solute that passes through the bed (see col. 9, lines 6-16). Thomas et al. further disclose that each of the flow paths can comprise a section (chamber 2, 7) comprising a second porous bed (see col. 3, lines 18-26 and col. 8, lines 52-60) placed upstream of the first porous bed. Thomas et al. disclose that the sections containing the first and second porous beds are physically separated from each other (see Fig. 1b). The beads (see col. 9, lines 6-16) contained within the chambers (2, 7, 3, 11) in the reference Thomas et al. can be construed as applicants' packed bed of particles, since

Art Unit: 1797

Thomas et al. implicitly disclose that the beads are sized to be introduced into microchannel elements (see col. 9, lines 6-16 and col. 3, lines 49-59). Thomas et al. disclose that the porous bed comprises a solid phase material (i.e. beads packed within chambers 2, 7, 3, 11) capable of functioning as a size exclusion material (see col. 9, lines 6-16 and col. 3, lines 49-59). Thomas et al. disclose that a portion of each of the plurality of flow paths has a flow path (8, 16, 12) devoid of porous bed (see Figs. 1b and 2). With respect to the limitation recited in claim 7, the limitations recited in the claim is directed to an intended use of the claimed device and does not structurally further limit the apparatus claim. Neither the manner of operating a device nor a material or article worked upon further limit an apparatus claim. See MPEP § 2114 and 2115. Further, process limitations do not have patentable weight in an apparatus claim. See *Ex parte Thibault*, 164 USPQ 666,667 (Bd. App. 1969) that states "Expressions relating the apparatus to contents thereof and to an intended operation are of no significance in determining patentability of the apparatus claim."

Regarding claim 11, Thomas et al. teach a microfluidic process carried out in a flow path of a microchannel structure as claimed (see Abstract). Thomas et al. disclose providing a flow path in a form that comprises a second porous bed positioned upstream of a first porous bed (see col. 3, lines 18-26 and col. 8, lines 52-60). Thomas et al. disclose transporting a liquid aliquot containing various substances through the porous beds so as to encounter an immobilized reactant formed on the surface of at least one of the porous beds (see col. 8, lines 52-60). Thomas et al. further disclose that the porous beds can be configured to effect a desired function such as effecting

Art Unit: 1797

interaction with a specific substance found in the liquid (see col. 3, lines 18-26 and col. 9, lines 6-16). Thomas et al. further disclose that second porous bed (i.e. the beads that are positioned in chamber 2, 7) is capable of interact with a substance (i.e. cells), but non-interactive (dummy) with respect to soluble analytes in the liquid (see col. 3, lines 18-26 and col. 5, lines 12-24).

Regarding claims 12-16, Thomas et al. disclose a microfluidic comprising a microchannel structure that comprises a plurality of flow paths (6) (see Fig. 1b). Thomas et al. disclose that each of the flow paths can comprise a porous bed I (3,11) that is common for all of the flow paths and each of the flow paths can comprise a porous bed II (2,7) which is upstream of porous bed I (see col. 8, lines 52-60 and Figs. 1b and 2). Thomas et al. further disclose that the porous beds can comprise a binding moiety such as one member of a specific binding pair including biotin. Thomas et al. further disclose that either member of the specific binding pair can be attached to the beads, which form the porous bed structure (see col. 9, lines 6-16). Thomas et al. disclose that only one flow path (6) comprises both porous bed I and porous bed II (see Figs. 1b, 2 and col. 8, lines 52-65).

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3, 4, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thomas et al. (WO 99/55827) as applied to claims 1 and 12 above, and further in view of Mehta et al. (US 6,632,655).

Note: The reference made below to Thomas et al. is to U.S. Patent No. 6,632,656 which is an equivalent of the reference WO 99/55827 above.

Regarding claims 3, 4 and 17, Thomas et al. does not specifically disclose that the upstream end of the first porous bed is abutted to the downstream end of the second porous bed nor is a porous membrane provided between the upstream end and

Art Unit: 1797

the downstream end. Mehta et al. disclose a microfluidic device comprising particle sets/porous beds (see Abstract). Mehta et al. disclose that the particle sets/porous beds can be fixed in position in microfluidic flow paths for use as affinity purification devices, molecular capturing devices or for other purposes including acting as blank particles, dummy particles, test particles (see col. 2, lines 26-50 and col. 3, lines 1-24). Mehta et al. further disclose that the end of a first particle set/porous bed can be provided to abut to an end of a second particle set/porous bed (see col. 2, lines 50-65 and Fig. 3B). Mehta et al. further disclose that particle sets/porous beds can be fixed in place by a porous matrix capable of inhibition particle/bead movement (see col. 13, lines 46-60). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teachings of Thomas et al. and Mehta et al. and provided a microfluidic device in configuration as claimed for the purpose of carrying out affinity purification and detection procedure of a liquid sample, because Mehta et al. discloses that the particle sets of their inventions are advantageous for use as affinity purification devices (see col. 2, lines 26-36 and col. 9, lines 28-38).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lessanework Seifu whose telephone number is (571)270-3153. The examiner can normally be reached on Mon-Thr 7:00am-5:30pm.

Art Unit: 1797

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on 571-272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. S./  
Examiner, Art Unit 1797

/Walter D. Griffin/  
Supervisory Patent Examiner, Art Unit 1797